

### **REMARKS**

The Office Action of April 7, 2005 has been reviewed and the comments therein were carefully considered. In this application, claims 1-28 are pending, and claims 1-28 stand rejected. Claims 1, 12, 16, and 19 have been amended. No new matter has been introduced into the application. As explained in more detail below, the Applicant submits that all claims are now in condition for allowance and respectfully request such action.

#### **Rejections under 35 U.S.C. § 112**

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Examiner states the phrases “the barrel having a single terminal” and “the female lure [sic] connector creating the single barrel terminal” lack proper antecedent basis in the claims.

In regards to the phrase “the barrel having a single terminal”, the Applicant has amended the claim to more clearly indicate “the hollow barrel having a single terminal”. The hollow barrel is clearly recited in the claim, thereby providing sufficient antecedent basis for the amendment.

In regards to the phrase “the female lure connector creating the single barrel terminal, the Applicant has amended the claims to recite “the female lure connector creating the single terminal”. As indicated above, the hollow barrel (or conduit) is clearly recited in the claims, thereby providing proper antecedent basis for the limitation. Moreover, independent claims 1, 12, 16 recite a barrel (Claim 20 recites a conduit) “having a single terminal”, thereby providing clear antecedent basis for the phrase “the single terminal”. In view of the Applicant’s amendments, the Applicant respectfully requests reconsideration and withdrawal of the rejection.

### **Specification**

The amendment filed 01/21/2005 is objected to under 35 U.S.C. 132 as allegedly introducing new matter into the disclosure of the invention. More specifically, the Office Action asserts the added phrases: “the barrel having a single terminal”; and “the female lure [sic] connector creating the single barrel terminal” are not supported in the specification. The Applicant traverses the objection in view of the Remarks below.

In regards to the phrase “the barrel having a single terminal”, the limitation has been amended to more clearly claim the relevant aspects of the present invention. The amended claim limitation “the hollow barrel having a single terminal” has adequate support in the specification as originally filed. Indeed, the specification is replete with examples showing a catheter with a hollow barrel having a single terminal. (see, e.g., Specification, pages 5-7; Figures 4-7, and 9). Figure 6 provides a cross-sectional view of one embodiment of the invention including a hollow barrel having a single terminal. The hollow barrel 22 includes a barrel lumen 24 that initiates at with a protrusion lumen 30 and terminates at the end of a female luer connector 40. Thus, in the illustrative embodiment, the female luer connector 40 creates the single hollow barrel terminal. Figure 6, therefore, also provides clear support for the amended limitation “the female lure connector creating the single terminal”.

Moreover, the specification indicates “[a] female luer connector 40 is attached to barrel 22 opposite protrusion 28.” (Specification, page 9) As evidenced in the relevant figures, the female luer connector that is opposite the protrusion lumen creates the only terminal. Indeed, there are no side ports or additional hollow pathways. In view of the foregoing, the Applicant respectfully requests reconsideration and withdrawal of the rejection.

**Rejections under 35 U.S.C. § 102**

Claims 1-28 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent No. 5,676,656 to Brimhall ("the '656 patent"). The Applicant traverses the rejection in view of the Remarks below.

The '656 patent discloses an introducer needle assembly where an over-the-needle IV catheter is mounted over an introducer needle. (*See* Col. 1, lines 8-21). The catheter 20 is affixed to a catheter hub 21, and the needle 40 is affixed to a needle hub 41. "The needle hub can take the form of a flashback chamber having a vent plug 42 affixed thereto." (Col. 2, lines 46-53) As one skilled in the art can appreciate, fluid flow into the flashback chamber is an indication of entry into a vein or other source of bodily fluid. In fact, the specification sets forth that after insertion of the needle, a "flashback of blood will be observed in the needle hub 41". (Col. 3, lines 45-47) Therefore, the flashback chamber or needle hub 41 is in fluid communication with the catheter, and is therefore considered at least one terminal. The specification also states the "[s]ide port 22 is in fluid communication with the lumen of catheter 20", thereby creating at least a second terminal to the catheter. (Col. 2, lines 56-57).

For at least the above reasons, the needle hub 41 of the '656 cannot be considered the single terminal to the barrel as alleged by the Examiner. (*See* Office Action dated 4/7/2005, Paragraph 7). In fact, the needle hub does not even have a female luer connector. Independent claims 1, 12, and 16 each include the limitation "the female luer connector creating the single barrel terminal."

Moreover, disclosed embodiments of the luer connector of the present application are angled away from the patient's scalp in the direction of the drip assembly line causing the single terminal. (Specification, Page 3; Figure 6). In contrast, neither of the terminals (the needle hub 41 and side port 22) of the catheter assembly disclosed in the '656 patent angle away from the patient's head or

extend away from the plane containing the anchoring protrusions. Indeed, the only possible conduit that may extend away from the assembly is the extension tube 50, which is connected to the far end of the side port.

In view of the Applicant's Remarks, the Applicant respectfully requests reconsideration of claims 1-28 and withdrawal of the rejection.

Claims 1-28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,697,914 to Brimhall ("the '914" patent"). The Applicant traverses the rejection in view of the Remarks below.

The '914 patent relates to introducer needle assembly where an over-the-needle IV catheter is mounted over an introducer needle (*See* Col. 1, lines 6-20). The catheter of the '914 patent, comprises a catheter hub 21 that extends beyond a side port 22, wherein each the catheter hub and the side port are in fluid communication and are distinct and separate terminals. Indeed, every claimed embodiment of the '914 patent comprises the limitation of:

a catheter hub in fluid communication with the catheter and having a proximal end and a distal end connected to the proximal end of the catheter, the catheter hub including a radially extending wing having a proximal end and a distal end and a side port in fluid communication with the catheter hub

(Claims 1, 8, and 11). In contrast, claims 1, 12, 16, 19 and 20 of the present application require the barrel or first conduit to have a single terminal, therefore, the Applicant respectfully requests reconsideration of claims 1-28 and withdrawal of the rejection.

Claims 1-28 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,935,110 to Brimhall ("the '110 patent").

The '110 patent relates to introducer needle assembly where an over-the-needle IV catheter is mounted over an introducer needle. (*See* Col. 1, lines 6-20). The device of the '110 patent comprises a needle hub that extends beyond the side port having the female luer connector. For at

least the above reason, the Applicant requests reconsideration of claims 1-28 and withdrawal of the rejection.

Claims 1-28 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 4,326,519 to D'Alo *et. al.*


The '519 patent relates to separable introducer needle assembly where an over-the-needle IV catheter is mounted over an introducer needle, wherein the needle may be separated from the catheter after venipuncture has occurred. (*See* Col. 1, lines 46-56). Although the needle of the device may be removed, the catheter assembly which remains comprises a catheter hub which extends beyond the side port having the female luer connector. For at least the above reason, the Applicant requests reconsideration of claims 1-28 and withdrawal of the rejection.

### CONCLUSION

All rejections having been addressed by this response. The Applicant respectfully submits that the instant application is in condition for allowance and respectfully solicits prompt notification of the same. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the number set forth below.

Respectfully submitted,

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